Complete Summary

GUIDELINE TITLE

The use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Nursing and Supportive Care. Pressure ulcer prevention. Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2003 Oct. 167 p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Pressure ulcers (also called pressure sores, bed sores, pressure injuries, or decubitus ulcers)

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Preventive Medicine
Surgery

INTENDED USERS

Allied Health Personnel
Health Care Providers
Hospitals
Patients
Physicians

GUIDELINE OBJECTIVE(S)

- To evaluate and summarise the clinical and cost evidence for the use of pressure-relieving devices in preventing pressure ulcers
- To highlight gaps in the research evidence
- To formulate evidence-based and, where possible, cost effective clinical practice recommendations on the prevention of pressure ulcers using pressure-relieving devices based on the best evidence available to the Guideline Development Group (GDG)
- To consider the resource implications of using pressure-relieving devices to prevent pressure ulcers

TARGET POPULATION

Individuals of all ages who are vulnerable to or at elevated risk of developing pressure ulcers (including those undergoing surgery and post-operative care)

Note: The guideline does not include recommendations on the treatment of existing pressure ulcers.

INTERVENTIONS AND PRACTICES CONSIDERED

Use of Pressure-Relieving or Pressure-Redistributing Devices to Prevent Pressure Ulcers

Low-tech Devices

1. Standard foam mattresses
2. Alternative foam mattresses/overlays (e.g., high-specification foam, viscoelastic, convoluted foam, cubed foam); these are conformable and aim to redistribute pressure over a larger contact area
3. Gel-filled mattresses/overlays
4. Fluid-filled mattresses/overlays
5. Fibre-filled mattresses/overlays.
6. Air-filled mattresses/overlays

High-tech Devices

1. Alternating pressure (AP) devices: the patient lies on air-filled sacs, which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; these devices may incorporate a pressure sensor
2. Air fluidised devices: warmed air is circulated through fine ceramic beads covered by a permeable sheet; these allow support over a larger contact area
3. Low air loss (LAL) devices: patients are supported on air-filled sacs inflated at a constant pressure, through which air can pass
4. Turning beds/frames (kinetic or profiling beds): beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting

Note: The guideline is relevant to, but does not cover, risk factors, skin inspection, seating or general positioning of patients (unrelated to pressure-relieving devices), and pressure-relieving aids (e.g., water-filled gloves). Although aspects of risk assessment related to the allocation of pressure-relieving devices are covered, the reader is referred to detailed discussion of this topic in the National Institute for Clinical Excellence (NICE 2001) guidelines Inherited Guideline B. Pressure Ulcer Risk Assessment and Prevention.

Pressure-relieving aids such as water-filled gloves, sheepskins, doughnut-type devices, cushions, limb protectors, and seating were not considered, as recommendations about their use have been issued by NICE (due for review in 2005). The NICE (2001) guidelines reported that there is insufficient evidence for sheepskins, wheelchair cushions, and limb protector pads as pressure-relieving devices.

MAJOR OUTCOMES CONSIDERED

- Incidence of new pressure ulcers
- Grades of new pressure ulcers
- Quality adjusted life year
- Quality of life
- Cost measures, including cost-effectiveness, costs of pressure-relieving devices, and costs of treating pressure ulcers

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence for Clinical Effectiveness

In April 2001, a Health Technology Assessment (HTA) review was published on pressure-relieving devices for the prevention and treatment of pressure ulcers. This review updated the earlier Cochrane systematic review (Beds, Mattresses and Cushions for Pressure Sore Prevention and Treatment). For the purposes of this

guideline, the HTA review was updated by the Cochrane Wounds Group (CWG)and National Collaborating Center for Nursing and Supportive Care (NCC-NSC) staff to provide the most up-to-date and rigorous source of clinical effectiveness evidence.

Types of Studies

- Randomised controlled trials (RCTs) comparing beds, mattresses, and overlays that measured the incidence of new pressure ulcers as an objective measure of outcome
- Economic evaluations were included only if they were part of an RCT.
- No restriction on the basis of language, publication status, or year of study

Search Strategy for Clinical Effectiveness

Nineteen electronic databases were searched between 1966 and June 1998 using a sensitive search strategy designed in collaboration with an information specialist from the Centre for Reviews and Dissemination (CRD).

Subsequently, the Specialist Trials Register of the CWG (compiled and regularly updated from searches of the Cochrane Controlled Trials Register), MEDLINE, Cinahl, Embase, etc., were searched up to October 2002.

The electronic search was supplemented by a hand search of five specialist wound care journals, twelve conference proceedings, and a search of systematic reviews held on the National Health Service (NHS) CRD Database of Abstracts of Reviews of Effectiveness (DARE). The bibliographies of all retrieved and relevant publications were searched for further studies. Relevant economic evaluations were searched to add economic-related search terms to those used in the search for clinical trials. Authors of trials were contacted and asked to provide details of any associated economic evaluations.

Details of the search strategy are given in Appendix 2 of the original guideline document.

Inclusion/Exclusion Process

Retrieved studies were assessed for relevance by a single reviewer and decisions on final inclusion checked by a second reviewer; disagreements were resolved by discussion with a third reviewer. Rejected studies were checked by the CWG.

Where study details were lacking, the authors were invited to provide further information.

Additional Evidence (Economic, Quality of Life, Epidemiology)

The aim of the cost-effectiveness review was to identify the most up-to-date information that was generalisable to the United Kingdom (UK) context, to facilitate the cost effectiveness modelling process. Cost data, economic evaluations, epidemiological and quality of life evidence were all sought as part of this review in order to comprehensively inform UK estimates and uncertainty ranges of the cost of pressure-relieving devices, cost of treating pressure ulcers,

and quality of life estimates. Consequently, searches were undertaken by the National Collaborating Center for Nursing and Supportive Care (NCC-NSC) to identify:

- Economic evaluations and costing studies of pressure ulcers and/or pressure-relieving devices (cost effectiveness review)
- Quality of life measures for patients who have pressure ulcers and/or who use pressure-relieving devices (quality of life review)
- Studies that may provide information about the absolute risk of developing pressure ulcers for different patient groups in the UK (epidemiological review)

For economic evaluations, randomized controlled trials (RCTs) were sought. For costing and quality of life studies the study design inclusion criteria were necessarily broad in order to maximise the likelihood of obtaining useful data. For the epidemiological studies, cohort designs were sought for incidence studies and cross-sectional designs for prevalence studies. For all topics, systematic literature search methods were used, covering a number of databases (see Appendix 2 of the original guideline document). Details concerning selection criteria for articles can be found in section 5 of the original guideline document.

Submission of Evidence Process

In March 2002, stakeholders registered with NICE were invited to submit a list of evidence for consideration to ensure that relevant material to inform the evidence base was not missed.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

For the update of the clinical effectiveness review, 54 articles were assessed for eligibility; seven relevant articles were data extracted and included. In total, 41 randomised controlled trials were included in the review, including the seven new studies identified (see Appendix 3 of the original guideline document). Twenty-one trials involved patients without pre-existing pressure ulcers (intact skin); four included patients with ulcers greater than stage 1; three included both patients with and without ulcers, and in 13 studies it was unclear.

Results of Search/Sift for Economic Evaluations and Cost Studies

Total number of hits: 1,352
Potentially relevant from title/abstract: 240
Full article ordered: 141
Final number of economic evaluations included: 3
Final number of costing studies included: 11

Results of Search/Sift for Quality of Life Studies

Total number of hits: 302
Potentially relevant from title/abstract: 9
Meets eligibility criteria: 9

Full article ordered and appraised: 9
Final number included: 7

Results of Search/Sift Process for Epidemiology Update

Total number of hits: 2,431
Potentially relevant from title/abstract: 182
Meets eligibility criteria from title/abstract: 30
Full article ordered and appraised: 20
Final number included: 15

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I: Evidence from meta-analysis of randomised controlled trials or at least one randomised controlled trial

II: Evidence from at least one controlled trial without randomisation or at least one other type of quasi-experimental study

III: Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Abstraction for Clinical Effectiveness

Data from included trials were extracted by two reviewers into preprepared data extraction tables. Discrepancies were discussed and resolved. The following data were extracted from each study:

- Patient inclusion/exclusion criteria
- Care setting
- Key baseline variables by group (e.g., age, sex, baseline risk, baseline area of existing ulcers)

- Description of the interventions and numbers of patients randomised to each intervention
- Description of any co-interventions/standard care
- Duration and extent of follow-up
- Outcomes (incidence and severity of new pressure ulcers)
- Acceptability and reliability of devices if reported

If data were missing from reports, then attempts were made to contact the authors to complete the information necessary for the critical appraisal. If studies were published more than once, the most detailed report was used as the basis of the data extraction.

Appraisal of Methodological Quality

The methodological quality of each trial was assessed by two researchers independently. The following quality criteria were used:

- Description of inclusion and exclusion criteria used to derive the sample from the target population
- Description of a priori sample size calculation
- Evidence of allocation concealment at randomisation
- Description of baseline comparability of treatment groups
- Outcome assessment stated to be blinded
- Incident ulcers described by severity grading as well as frequency (stage 1 ulcers are not breaks in the skin and are subject to more inter-rater variation)
- Clear description of main interventions

Data Synthesis

For each trial, relative risk (RR) was calculated for outcomes such as number of patients developing ulcers and number of pressure ulcers healed; 95% confidence intervals (95% CIs) were included when sufficient detail allowed their calculation. The results from replicated studies were plotted onto graphs and discussed by narrative review. Unique comparisons were not plotted and the relative risk is stated in the text. Individual study details are presented in the evidence table (Appendix 3 of the original guideline document). Where there was more than one trial comparing similar devices using the same outcome, and in the absence of obvious methodological or clinical heterogeneity, statistical heterogeneity was tested for by chi-squared test. In the absence of significant statistical heterogeneity, studies with similar comparisons were pooled using a fixed effects model (Clarke M, & Oxman AD, eds. Summarising effects across studies. Cochrane Reviewers Handbook 4.0 [updated July 1999]; Section 8.3. In: The Cochrane Library [database on CD-ROM]. The Cochrane Collaboration. Oxford: Update Software; 2000, issue 1). If heterogeneity was observed, both random and fixed effects models were used to pool the data. All statistical analysis was performed on Revman (v3.1.1) and conducted by the Cochrane Wounds Group (CWG).

Evidence Synthesis and Grading

For the update of the clinical effectiveness reviews, data from existing trials of effectiveness of pressure-relieving devices were synthesised with new trials in a

narrative review. There were insufficient trials to necessitate the re-analysis of existing meta-analyses. The data from included studies pertaining to costs, economic evaluation, epidemiology, and quality of life were also qualitatively synthesised into a narrative format. Information from the reviews on costs, economic evaluations, and epidemiology was used in the economic modelling. All included studies are summarised in evidence tables (Appendices 7 to 9 of the original guideline document) as well as discussed in the appropriate evidence reviews.

Evidence gradings were assigned to each evidence review using the evidence hierarchy shown in the field titled "Rating Scheme for the Strength of the Evidence" in this summary and in Table 2 of the original guideline document, which is the only hierarchy recommended by the National Institute for Clinical Excellence (NICE) at the time of writing. (It should be noted that the hierarchy strictly applies to questions of effectiveness.)

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guideline Development Group (GDG)

The guideline recommendations were developed by a multidisciplinary and lay Guideline Development Group (GDG) convened by the National Institute for Clinical Excellence (NICE)-funded National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) with membership approved by NICE. Members included representatives from:

- patient groups
- nursing
- field of tissue viability and wound care
- medicine
- allied health
- researchers
- staff from the NCC-NSC

The GDG met six times between May 2002 and July 2003. An additional meeting to formulate patient-related review questions relating to the guideline topic was held in July 2002.

Formulating and Grading Recommendations

In order for the GDG to formulate a clinically useful recommendation, it was agreed that the following factors be considered:

- The best available evidence, with preference given to empirical evidence over expert judgement, including:
    - a profile of the cost data

    - results of economic modelling
    - effectiveness data taking into account the strength of evidence (level, quality, precision) as well as the size of effect and relevance of the evidence
    - where reported, data regarding additional outcomes, such as comfort, adverse effects, and patient acceptability, associated with the use of pressure-relieving devices
- A comparison between the outcomes for alternative interventions where possible (this was limited because key comparisons such as between high-tech devices and high-specification foam mattresses are not available)
- The feasibility of interventions, including the cost of the intervention; acceptability to clinicians, patients, and carers; and appropriateness of device
- The balancing of benefits against risks including, where reported, all patient-relevant endpoints (including adverse effects, comfort, and acceptability where reported) and the results of the economic modelling
- The applicability of the evidence to groups defined in the scope of the guideline, having considered the profile of patients recruited to the trials and data obtained from our review of the epidemiological data and quality of life literature

This information was presented to the group in the form of evidence tables and accompanying summaries, which were discussed at GDG meetings. Where the GDG identified issues that impacted on considerations of the evidence and the ability to formulate implementable and pragmatic guideline recommendations, these were summarised in the GDG commentary sections.

The GDG agreed that the existing Royal College of Nursing (RCN) guideline recommendations on pressure-relieving devices would provide a useful starting point for formulating recommendations in the light of the additional evidence pertaining to clinical effectiveness and the new economic evidence. These guideline recommendations were subsequently revised to reflect the views of the GDG and their interpretation of the current evidence. Issues with the data, interpretation of the evidence, and the wording were discussed until there was agreement on the wording and grading.

Where the GDG decided that hard evidence was essential before any recommendations could be considered, recommendations for future research were made (see Section 7 of the original guideline document). The group then ranked these in order of importance so that the top five could be included in the NICE version. As described in the original guideline document, there were shortcomings in the data, and so some of the review questions could not be fully and satisfactorily answered by empirical evidence. In some instances extrapolated evidence was used; this sometimes resulted in Level I evidence being graded as Level IV, particularly where the evidence was extrapolated beyond trial subjects and settings (see Section 6 of the original guideline document). The grading of the recommendations was agreed at a GDG meeting, using the scheme described in the section of this summary titled "Rating Scheme for the Strength of the Recommendations" and in Table 8 of the original guideline document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

*Recommendation Grades

A: Directly based on category I evidence

B: Directly based on:

- category II evidence, or
- extrapolated recommendation from category I evidence

C: Directly based on:

- category III evidence, or
- extrapolated recommendation from category I or II evidence

D: Directly based on:

- category IV evidence
- extrapolated recommendation from category I, II, or III evidence

**Grading Scheme

Evidence

1: Generally consistent finding in a majority of multiple acceptable studies

2: Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies

3: Limited scientific evidence that does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes expert opinion.

*From Eccles M, Mason J. (2001) How to develop cost conscious guidelines. Health Technology Assessment 5(16).

**Adapted from Waddell G, Feder G, McIntosh A, et al (1996) Low Back Pain Evidence Review. London: Royal College of General Practitioners.

COST ANALYSIS

Cost Effectiveness Review Methods

To fulfill the Department of Health (DoH) and Welsh Assembly Government remit, the National Institute for Clinical Excellence (NICE) requested that the cost-effectiveness evidence of pressure-relieving devices be assessed. In accordance with the objectives of the scope, cost effectiveness was addressed in the following way:

- A comparison of the cost and cost effectiveness of pressure-relieving beds, mattresses, and overlays compared with standard support surfaces
- An investigation of which types of pressure-relieving surfaces are the most cost effective for prevention of pressure ulcers

Incremental Cost Per Pressure Ulcer Averted

In the first instance, the incremental cost effectiveness between different devices could be reported in terms of the incremental cost per pressure ulcer averted. This is a ratio of the difference in costs to the health service of using different devices divided by the difference in the number of pressure ulcers averted. The cost to the health service includes any savings derived through using pressure-relieving devices:

$$= \frac{\text{Difference in costs to the health service between pressure-relieving devices}}{\text{Difference in number of pressure ulcers averted}}$$

Incremental Cost Per Quality-Adjusted Life Year (QALY)

If possible, the likely decrement in QALYs associated with a pressure ulcer of a particular stage could be estimated and cost effectiveness then be reported in terms of the cost per QALY gained. Costs incurred by patients and their informal carers is documented and reported where available:

$$= \frac{\text{Difference in costs to the health service between pressure-relieving devices}}{\text{Difference in QALYs}}$$

Information requirements for cost effectiveness models (incremental cost per pressure ulcer averted and incremental cost per QALY) included the following:

- Comparison of the relative risk of developing a pressure ulcer between devices
- Epidemiology of the absolute risk of developing a pressure ulcer for patient groups
- Cost of device per patient
- Cost of treating pressure ulcers
- Estimate of QALYs

Results of the cost-effectiveness evidence retrieval and appraisal can be found in section 5.7 of the original guideline document. A simple cost-effectiveness model is also presented. The model highlighted a lack of evidence for key model parameters for estimating the cost effectiveness of different pressure-relieving devices.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (the full guideline, National Institute for Clinical Excellence [NICE] guideline, and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the full guideline, the NICE guideline, and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evidence categories (I-IV) and recommendation grades (A-D and 1-3) are defined at the end of the Major Recommendations field.

Risk Assessment and Prevention

Identifying Individuals Vulnerable to or at Elevated Risk of Pressure Ulcers

3 - Assessing an individual's risk of developing pressure ulcers should involve both informal and formal assessment procedures.

3 - Risk assessment should be carried out by personnel who have undergone appropriate training to recognise the risk factors that contribute to the development of pressure ulcers and know how to initiate and maintain correct and suitable preventative measures.

3 - The timing of risk assessment should be based on each individual case. However, it should take place within 6 hours of the start of admission to the episode of care.

3 - If an individual is considered not to be vulnerable to or at elevated risk of pressure ulcers on initial assessment, reassessment should occur if there is a change in an individual's condition that increases risk (see recommendations under "Risk Factors" below).

3 - All formal assessments of risk should be documented/recorded and made accessible to all members of the interdisciplinary team.

Use of Risk Assessment Tools

1 - Risk assessment tools should only be used as an aide memoire and should not replace clinical judgment.

If use of a risk assessment tool is preferred (to assist clinical judgment), it is recommended that a scale that has been tested for use in the same specialty is chosen.

Risk Factors

2 - An individual's potential to develop pressure ulcers may be influenced by the following intrinsic risk factors, which therefore should be considered when performing a risk assessment:

- Reduced mobility or immobility
- Sensory impairment
- Acute illness
- Level of consciousness
- Extremes of age
- Vascular disease
- Severe chronic or terminal illness
- Previous history of pressure damage
- Malnutrition and dehydration

2 - The following extrinsic risk factors are involved in tissue damage and should be removed or diminished to prevent injury: pressure, shearing, and friction.

2 - The potential of an individual to develop pressure ulcers may be exacerbated by the following factors, which therefore should be considered when performing a risk assessment: medication and moisture to the skin.

Patient Factors to Consider in Selecting Pressure-relieving Device

D - Decisions about which pressure-relieving device to use should be based on cost considerations and an overall assessment of the individual. Holistic assessment should include all of the following and should not be based solely on scores from risk assessment tools:

- Identified levels of risk
- Skin assessment
- Comfort
- General health state
- Lifestyle and abilities
- Critical care needs
- Acceptability of the proposed pressure-relieving equipment to the patient and/or carer

Provision for All Individuals Vulnerable to Pressure Ulcers

B - All individuals assessed as being vulnerable to pressure ulcers should, as a minimum provision, be placed on a high-specification foam mattress with pressure-relieving properties

Patients at Elevated Risk of Developing Pressure Ulcers

D - Although there is no research evidence that high-tech pressure relieving mattresses and overlays are more effective than high-specification (low-tech) foam mattresses and overlays, professional consensus recommends that consideration should be given to the use of alternating pressure or other high-tech pressure-relieving systems:

- As a first-line preventative strategy for people at elevated risk as identified by holistic assessment
- When the individual's previous history of pressure ulcer prevention and/or clinical condition indicates that he or she is best cared for on a high-tech device
- When a low-tech device has failed

Patients Undergoing Surgery

D - All individuals undergoing surgery and assessed as being vulnerable to pressure ulcers should, as a minimum provision, be placed on either a high-specification foam theatre mattress or other pressure-redistributing surface.

Repositioning and 24-hour Approach to Provision of Pressure-Relieving Devices

D - The provision of pressure-relieving devices needs a 24- hour approach. It should include consideration of all surfaces used by the patient

D - Support surface and positioning needs should be assessed and reviewed regularly and determined by results of skin inspection, patient comfort, ability, and general state. Thus repositioning should occur when individuals are on pressure relieving devices

D - The management of a patient in a sitting position is also important. Even with appropriate pressure relief, it may be necessary to restrict sitting time to less then 2 hours until the condition of an individual with elevated risk changes

Coordinated Time Specified Approach

D - A pressure ulcer reduction strategy should incorporate a coordinated approach to the acquisition, allocation, and management of pressure-relieving equipment. The time elapsing between assessment and use of the device should be specified in this strategy.

Education and Information-giving

D - All healthcare professionals should be educated about:

- Pressure ulcer risk assessment and prevention
- Selection, use, and maintenance of pressure-relieving devices
- Patient education and information giving

D - Individuals vulnerable to or at elevated risk of developing pressure ulcers and their carers should be informed verbally and in writing about:

- The prevention of pressure ulcers using pressure-relieving strategies
- The use and maintenance of pressure-relieving devices
- Where they can seek further advice and assistance

Definitions:

Evidence Categories

I: Evidence from:

- meta-analysis of randomised controlled trials, or
- at least one randomised controlled trial

II: Evidence from:

- at least one controlled study without randomisation, or
- at least one other type of quasi-experimental study

III: Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies

IV: Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Recommendation Grades

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Grading Scheme

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3: Limited scientific evidence that does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes expert opinion.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for pressure ulcer risk assessment and prevention.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Although the guideline does not cover treatment of existing pressure ulcers, its recommendations will be useful in preventing pressure ulcers on other areas of the patient's body and further pressure damage to existing pressure ulcers.
- Prevention of pressure ulcers has benefits for both the health-related quality of life of the patient/carer and the health services.

Subgroups Most Likely to Benefit

Groups at high risk of developing a pressure ulcer generally include those with the following intrinsic risk factors:

- Reduced mobility or immobility
- Sensory impairment
- Acute illness
- Level of consciousness
- Extremes of age
- Previous history of pressure damage
- Vascular disease
- Severe chronic or terminal illness
- Malnutrition

POTENTIAL HARMS

Equipment safety is an important issue in relation to the use of pressure-relieving devices. In particular, cross-infection can happen if equipment is inadequately decontaminated between patients and injury is possible if users of such equipment

(patients, carers, and healthcare professionals) have not been educated about appropriate use.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- As with any clinical guideline, recommendations may not be appropriate for use in all circumstances. One limitation of a guideline is that it simplifies clinical decision-making. Decisions to adopt any particular recommendations must be made by practitioners in the light of:
    - Available resources
    - Local services, policies, and protocols
    - The patient's circumstances and wishes
    - Available personnel and devices
    - Clinical experience of the practitioner
    - Knowledge of more recent research findings
- The recommendations in this document are not designed to be used as a "stand-alone" product and should be used in conjunction with the existing National Institute for Clinical Excellence (NICE 2001) guideline on risk assessment and prevention, which can be found on the NICE Web site at: http://www.nice.org.uk/pdf/clinicalguidelinepressuresoreguidancercn.pdf.
- Healthcare professionals should use their clinical judgement and consult with patients when applying the recommendations, which aim to reduce the negative physical, social, and financial impact of pressure ulcers.

Terminology

1. Where the term "carer" is used, this refers to unpaid carers as opposed to paid carers (e.g., care workers).
2. There is much debate in the literature and amongst experts about the appropriateness of the term "pressure-relieving." For the purposes of this guideline, "pressure-relieving" is used as an umbrella term for all pressure-reducing and pressure-redistributing devices. The term is also consistent both with recent guidelines and the evidence review on which this guideline is partly based. A glossary of pressure-relieving devices is given in Appendix 1 of the original guideline document.
3. Pressure ulcers have also been known previously as pressure sores, bedsores, decubitus ulcers, and pressure injuries.
4. The Guideline Development Group (GDG) decided to use the terms "vulnerable to pressure ulcers" and "at elevated risk of pressure ulcers" rather than the commonly used terms "at risk" and "at very high risk." The latter terms imply that there are reliable cut-off points for identifying risk, yet there is little evidence to show that using a pressure ulcer risk scale alone is better than clinical judgement for assessing risk or that allocation of pressure-relieving devices can be linked to risk assessment scales. "Vulnerable to pressure ulcers" means someone who is likely to develop pressure ulcers unless special care is given (special care meaning a planned intervention following holistic assessment); "at elevated risk of pressure ulcers" means someone who is especially likely to develop pressure ulcers unless special care is given.

5. Pressure-relieving devices can be divided into low-tech and high-tech devices.*

Low-tech devices. These provide a conforming support surface that distributes the body weight over a large area, and include the following:

- Standard foam mattresses
- Alternative foam mattresses/overlays (e.g., high-specification foam, viscoelastic, convoluted foam, cubed foam); these are conformable and aim to redistribute pressure over a larger contact area.
- Gel-filled mattresses/overlays
- Fluid-filled mattresses/overlays
- Fibre-filled mattresses/overlays
- Air-filled mattresses/overlays

High-tech devices. These are dynamic systems that include the following:

- Alternating pressure devices: the patient lies on air-filled sacs, which sequentially inflate and deflate and relieve pressure at different anatomical sites for short periods; these devices may incorporate a pressure sensor.
- Air fluidised devices: warmed air is circulated through fine ceramic beads covered by a permeable sheet; these allow support over a larger contact area.
- Low air loss devices: patients are supported on air-filled sacs inflated at a constant pressure, through which air can pass.
- Turning beds/frames (kinetic or profiling beds): beds that either aid manual repositioning of the patient or reposition the patient by motor-driven turning and tilting.

*From Cullum N, Nelson EA, Sheldon T (2001) Systematic reviews of wound care management (5): pressure-relieving beds, mattresses and cushions for the prevention and treatment of pressure sores. In Cullum N, Nelson EA, Flemming K et al. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. Health Technology Assessment 5(9).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation in the National Health Service

Local health communities should review their existing service provision for pressure ulcer risk assessment and prevention including the use of pressure-relieving devices (beds, mattresses, and overlays) for the prevention of pressure ulcers in primary and secondary care as they develop their Local Delivery Plans. The review should consider the resources required to implement the recommendations set out in the original guideline document and described in the "Major Recommendations" field above, the people and processes involved, and the timeline over which full implementation is envisaged. It is in the interests of patients that the implementation timeline is as rapid as possible.

Relevant local clinical guidelines and protocols should be reviewed in the light of this guidance and revised accordingly.

Suggested audit criteria for the use of pressure-relieving devices are listed in Section 8 of the original guideline document. These can be used as the basis for local clinical audit, at the discretion of those in practice.

Dissemination of the Guideline

The guideline has been produced in both full and summary formats and as a version for the public (Information for the Public). Full copies of the guideline are available through the NICE Web site (http://www.nice.org.uk) in Portable Document Formant (PDF) and the summary through the National Electronic Library for Health (NeLH) (http://www.nelh.nhs.uk/) and National Guideline Clearinghouse (http://www.guideline.gov).

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Nursing and Supportive Care. Pressure ulcer prevention. Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2003 Oct. 167 p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Oct

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Nursing and Supportive Care - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Groups

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the guideline development group (GDG) were required to make formal declarations of interest at the outset, which were recorded. GDG members were also asked to declare interests at the beginning of each GDG meeting. This information is recorded in the meeting minutes and kept on file at the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455, ref: N0330. 11 Strand, London, WC2N 5HR.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Nursing and Supportive Care. Pressure ulcer prevention. Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. London (UK): National Institute for Clinical Excellence (NICE); 2003 Oct. 35 p. (Clinical Guideline; no. 7). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Clinical Excellence (NICE) Web site
- Pressure ulcers and pressure relieving devices--some common questions and answers. National Institute for Clinical Excellence, 2003 Oct. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Pressure ulcer prevention. Pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care. Clinical practice algorithms. National Institute for Clinical Excellence, 2003 Oct. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Section 8 of the original guideline document.

PATIENT RESOURCES

The following is available:

- Pressure ulcers: prevention and pressure-relieving devices: Understanding NICE guidance - information for people at risk of pressure ulcers, their carers, and the public. National Institute for Clinical Excellence (NICE), 2003 Oct. 23 p.

Electronic copies: Available from the National Institute for Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS), 11 Strand, London, WC2N 5HR. Response Line 0870 1555 455, ref N0479.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on July 13, 2004. The information was verified by the guideline developer on November 26, 2004.

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